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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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HAMRE, SCHUMANN, MUELLER & LARSON, P.C.
P.O. BOX 2902
MINNEAPOLIS, MN 55402-0902

EXAMINER	
ARIANI, KADE	
ART UNIT	PAPER NUMBER
1651	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,291	YONEHARA ET AL.	
	Examiner	Art Unit	
	Kade Ariani	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-30 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-30 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A reference to any prior application to which applicant is claiming priority must be inserted as the first sentence of the specification.

Claims 1-30 are pending in this application and were examined on their merits.

Specification

The amendment filed on October 12, 2004 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C.132 (a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: page 19 line 7-21 in the last line of the paragraph, replacing (WO 99/20039) by (WO 97/20039).

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to a method of **measuring** an amount of a glycated protein in a sample where the claim recites "degrading a glycated protein by fructosyl amino acid oxidase via a redox reaction in the presence of a tetrazolium compound and sodium azide and removing the glycated amino acid and measuring the redox reaction to determine the amount of glycated protein", but, since the claim does not set forth any steps involved in the measuring an amount of a glycated protein in a sample via measuring the redox reaction, it is unclear what method applicant is intending to encompass. A claim is indefinite where it merely recites components of a reaction mixture without any active, positive steps delimiting how this method actually practiced and so it is unclear how the applicant is intending to perform the measurement.

Claim 6 recites a method of claim 1 wherein a solution containing the tetrazolium compound and sodium azide **is aged** before being added to the sample. Since the claim does not set forth any steps to explain the aging, therefore it is unclear how the applicant is intending to perform the process.

Double Patenting Rejections

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not

identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of Yonehara et al. US Patent No. 6,790,665. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are reciting the same invention.

Claims 1-22 of Yonehara et al. recite **a method of determining a ratio of glycated hemoglobin to total hemoglobin** in a sample comprising: determining an

amount of total hemoglobin in a sample containing **glycated hemoglobin** by causing a **redox reaction** between a glycation site of the denatured hemoglobin obtained and a **fructosyl amino acid oxidase**, measuring the degree to which the **redox reaction** has occurred to determine an amount of the glycated hemoglobin, and calculating a ratio of the glycated hemoglobin to the total hemoglobin in the sample from the amount of the total hemoglobin and the amount of the glycated hemoglobin, wherein the denatured **hemoglobin is treated with a protease**, the hemoglobin in the sample is treated with the tetrazolium compound in the presence of **a surfactant**, **the tetrazolium compound is 2-(4-iodophenyl)-3- (2,4-dinitrophenyl)-5-(2,4-disulfophenyl)-2H-tetrazolium salt**, a method wherein the color-developing substance is a substrate that develops color by oxidation and has developed color as a result of a reaction caused by an oxidase between the hydrogen peroxide and the substrate.

It would have been obvious to one skilled in the art at the time the invention was made to use the claimed method disclosed by Yonehara et al. to measure an amount of glycated protein in a sample using a redox reaction.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komori et al. (European patent application, EP1 002874 A2, Published June 24th, 2000) in view Montellano et al. (Biochemistry, 1988, Vol. 27, pp. 5470-5476) and further in view of Ishimaru et al. (Patent number 6,127,138, Date of Patent Oct. 3, 2000).

Claims 1-8 are drawn to a method of measuring an amount of a glycated protein in a sample while claims 9-30 are drawn to a kit utilizing the claimed method of claims 1-8 to measure a glycated protein.

Claim 1 is drawn to a method of measuring an amount of a glycated protein in a sample, comprising: causing a fructosyl amino acid oxidase to act on a glycated amino acid present in the sample other than the glycated protein so as to remove the glycated amino acid by degrading it; then causing a fructosyl amino acid oxidase to act on the glycated protein to cause redox reaction in the presence of a tetrazolium compound and sodium azide; and measuring the redox reaction to determine the amount of the glycated protein.

Claim 2 is the method according to claim 1, wherein the glycated protein is glycated hemoglobin.

Claim 3 is the method according to claim 1, further comprising: degrading the glycated protein with a protease to give a degradation product of the glycated protein

either before or after causing the fructosyl amino acid oxidase to act on the glycated amino acid, wherein the fructosyl amino acid oxidase caused to act on the glycated protein is caused to act on the degradation product to cause the redox reaction.

Claim 4 is drawn to the method according to claim 1, wherein the measurement of the redox reaction is measurement of an amount of hydrogen peroxide formed by causing the fructosyl amino acid oxidase to act on the glycated protein, the measurement of the amount of the hydrogen peroxide comprising: adding N-(carboxymethylaminocarbonyl)-4,4'-bis(dimethylamino) diphenylamine sodium salt as a color-developing substrate to a reaction solution of the redox reaction in the presence of a surfactant, thereby causing a redox reaction between the color-developing substrate and the hydrogen peroxide; and measuring an amount of color developed by the color-developing substrate to determine the amount of the hydrogen peroxide, wherein, a concentration of the tetrazolium compound in the reaction solution is in a range from 0.5 to 8 mmol/1, a concentration of the sodium azide in the reaction solution is in a range from 0.08 to 0.8 mmol/1, a concentration of the surfactant in the reaction solution is in a range from 0.3 to 10 mmol/1, and a pH of the reaction solution is in a range from 7.0 to 8.5.

Claim 5 is drawn to the method according to claim 1, wherein the fructosyl amino acid oxidase caused to act on the glycated amino acid is specific for a glycated α-amino group, and the fructosyl amino acid oxidase caused to act on the glycated protein is

specific for a glycated α-amino group and a glycated side chain of an amino acid residue.

Claim 6 is drawn to the method according to claim 1, wherein a solution containing the tetrazolium compound and the sodium azide is aged and is then added to the sample.

Claim 7 is drawn to the method according to claim 1, wherein the tetrazolium compound is 2-(4-iodophenyl)-3-(2,4-dinitrophenyl)-5- (2,4-disulfophenyl)-2H-tetrazolium salt.

Claim 8 is drawn to a method of determining a ratio of glycated hemoglobin to hemoglobin, comprising: measuring an amount of glycated hemoglobin in a sample by the method according to claim 1; measuring an amount of hemoglobin in the sample; and calculating the ratio of the glycated hemoglobin to the hemoglobin using the amount of the glycated hemoglobin and the amount of the hemoglobin thus measured.

Claims 9-11 are drawn to a measuring kit used for measuring a glycated protein using a redox reaction, comprising: a pretreatment reagent for pretreating a sample, containing a fructosyl amino acid oxidase; and a color-developing reagent containing a fructosyl amino acid oxidase, an oxidoreductase, and a color-developing substrate, wherein the glycated protein is glycated hemoglobin, the fructosyl amino acid oxidase contained in the pretreatment reagent is specific for a glycated a-amino group, and the fructosyl amino acid oxidase contained in the color-developing reagent is specific for a glycated a-amino group and a glycated side chain of an amino acid residue.

Claims 12- 15 are drawn to the measuring kit according to claim 9, further comprising a protease reagent containing a protease, wherein the protease is at least one protease selected from the group consisting of metalloproteinases, bromelain, papain, trypsin, proteinase K, subtilisin, and aminopeptidase, wherein the protease is at least one protease that degrades glycated hemoglobin selectively and is selected from the group consisting of metalloproteinases, bromelain, papain, trypsin derived from porcine pancreas, and protease derived from Bacillus subtilis, and a measuring kit wherein the protease reagent further contains a tetrazolium compound and sodium azide.

Claims 16-17 are drawn to the measuring kit according to claim 15, wherein, in the protease reagent, the tetrazolium compound (A) and the sodium azide (B) are present at a ratio (molar ratio A: B) in a range from 20: 3 to 20: 12, wherein the protease reagent contains a metalloproteinase as the protease and further contains Ca and Na, and a concentration of the metalloproteinase is in a range from 100 to 40,000 KU/1, a concentration of Ca is in a range from 0.1 to 50 mmol/1, and a concentration of Na is in a range from 5 to 1000 mmol/1.

Claims 18-23 are drawn to the measuring kit according to claim 9, wherein the color-developing substrate is N- (carboxymethylaminocarbonyl)-4,4'-bis(dimethylamino) diphenylamine sodium salt, wherein at least one of the pretreatment reagent and the color-developing reagent further contains a surfactant, the protease reagent further contains a surfactant, the surfactant is at least one surfactant selected from the group

consisting of polyoxyethylene ethers, polyoxyethylene phenol ethers, polyoxyethylene sorbitan alkyl esters, and polyoxyethylene alkyl ethers, the pretreatment reagent further contains at least one buffer selected from the group consisting of CHES, MOPS, TAPS, EPPS, phosphate, HEPPSO, POPSO, and borate, and a pH of the pretreatment reagent is in a range from 8.0 to 10.0, the color-developing reagent further contains at least one buffer selected from the group consisting of MES, Tris, phosphate, MOPS, TES, HEPES, HEPPSO, and EPPS, and a pH of the color- developing reagent in a range from 6.0 to 9.0.

Claim 24 is drawn to the measuring kit according to claim 12, wherein the protease reagent further contains at least one buffer selected from the group consisting of Tris, MES, DIPSO, TES, POPSO, HEPES, MOPSO, Bis-Tris, MOPS, ADA, PIPES, ACES, and phosphate, and a pH of the protease reagent is in a range from 5.0 to 7.0.

Claim 25 is drawn to the measuring kit according to claim 15, wherein the tetrazolium compound is 2-(4-iodophenyl)-3-(2,4-dinitrophenyl)-5-(2,4-disulfophenyl)-2H- tetrazolium salt.

Claim 26 is drawn to the measuring kit according to claim 9, wherein the pretreatment reagent further contains at least one of uricase and bilirubin oxidase.

Claim 27 is drawn to the measuring kit according to claim 9, wherein the color-developing reagent further contains sodium azide.

Claim 28 is drawn to the measuring kit according to claim 22, wherein the fructosyl amino acid oxidase in the pretreatment reagent is specific for a glycated a-amino group; in the pretreatment reagent, a concentration of the fructosyl amino acid oxidase is in a range from 10 to 5000 U/1 and a concentration of the buffer is in a range from 5 to 200 mmol/1; and a pH of the pretreatment reagent is in a range from 8.0 to 10.0.

Claim 29 is drawn to the measuring kit according to claim 15, wherein the protease reagent further contains Ca, Na, and a buffer; the protease in the protease regent is a metalloproteinase; in the protease regent, a concentration of the metalloproteinase is in a range from 100 to 10,000 KU/I, a concentration of the tetrazolium compound is in a range from 0.1 to 10 mmol/I, a concentration of the sodium azide is in a range from 0.08 to 4 mmol/1, a concentration of Ca is in a range from 0.1 to 50 mmol/1, a concentration of Na is in a range from 5 to 1000 mmol/1, and a concentration of the buffer is in a range from 0.1 to 500 mmol/1; and a pH of the protease reagent is in a range from 5.0 to 7.0.

Claim 30 is drawn to the measuring kit according to claim 23, wherein, in the color-developing reagent, the fructosyl amino acid oxidase is specific for a glycated a-amino group and a glycated side chain of an amino acid residue, the oxidoreductase is a peroxidase, and the color-developing substrate is N- (carboxymethylaminocarbonyl)-4,4'-bis(dimethylamino) diphenylamine sodium salt; in the color-developing reagent, a concentration of the fructosyl amino acid oxidase is in a range from 100 to 50,000 U/I, a

concentration of the peroxidase is in a range from 0.1 to 400 KU/l, a concentration of the N-(carboxymethylaminocarbonyl)-4,4'- bis(dimethylamino)diphenylamine sodium salt is in a range from 0.02 to 2 mmol/1, and a concentration of the buffer is in a range from 10 to 500 mol/1; and a pH of the color-developing reagent is in a range from 6 to 9.

Komori et al. discloses "**a method of measuring glycated proteins in a sample**, particularly **glycated hemoglobin using a redox reaction** by **treating the glycated protein and glycated amino acid (Page 4, 0029) with fructosyl amino acid oxidases (FAOD) to form hydrogen peroxide** and **measuring the amount of the product based on the action of the enzyme**" (Page 2, lines 1, and 5-13, and 35-36). Komori et al. further recites a formula representing the reaction that is catalyzed by FAOD (Page 4, 0031) and recites the FAOD can act when an α-amino group is glycated (Page 6, 0034) or other amino group being glycated (Page 6, 0033).

Komori et al. discloses "adding **a tetrazolium compound prior to the redox reaction** or pretreating a sample with a tetrazolium compound to eliminate the influence of any reducing substance" (Page 2 Line 36 and page 8 lines 17 &18) and further discloses the formation of hydrogen peroxide due to the oxidation of glycated proteins by the action of FAOD enzyme, and further recites both glycated peptides (proteins) and glycated amino acids can be subjected to the action of FAOD and glycated proteins and peptides are **treated with a protease before its treatment with FAOD** (Page 4, Lines 7-9).

Komori et al. recites **N- (carboxymethylaminocarbonyl)-4,4'-bis(dimethylamino) diphenylamine sodium salt (DA-64) as the color developing**

substrate (Page 4, Lines 3-5) and discloses adding **a surfactant** so that its concentration in the treating solution falls in the range of 0.01- 5% by weight (Page.6 Line 5) and the concentration of tetrazolium compound (WST-3) is 1 mmol/L (Page 8, Lines 26 and 27).

Komori et al. recites erythrocytes are hemolyzed to prepare a sample and the hemolyzed sample is treated with **a suitable protease** (examples proteinase K, subtilisin, trypsin, aminopeptidase (page 6, 0052)) and the FAOD to form hydrogen peroxide, finally the quantity of the hydrogen peroxide formed corresponds to the quantity of glycated hemoglobin, Komori et al. discloses a peroxidase (POD) having a concentration equal to 219 KU/L (Page 17, 0095) and a reducing agent are added to the sample (Page 2, Line 12).

Sigma-Aldrich catalogue discloses an active form of metalloproteinase in 10mM MES buffer, containing 0.25 mM sodium chloride and 5 mM calcium chloride and 0.01% sodium azide.

Komori et al teaches **non-ionic surfactants** such as Triton X-100 series, Tween series, Brij series and the like (page 5-6, 0044). The **pretreatment is usually carried in a buffer** and further recites CHES, CAPSO, CAPS, phosphate, Tris, EPPS, HEPES, pH range 8-12 (Page 6, 0047).

Komori et al. teaches FAOD treatment is carried out in the protease treatment solution for which a Tris-HCl, EPPS, or PIPES buffer can be used and the concentration of FAOD in the reaction solution is 50-50,000 U/L and pH of 6-9 (Page 6, 0052,0055)

and 0.146 mM DA-64 (Page 17, 0095). Komori et al. also recites **uricase** (page7, 0066) and bilirubin oxidase (Page 7, 0064).

Komori et al. does not teach a measuring kit, aging a solution containing tetrazolium compound and sodium azide. However, Montellano et al. teaches azide anion functions as an inhibitor of catalytic hemoproteins like catalase and horseradish peroxidase and using 0.15-0.6 mM sodium azide (Pg 5470 Introduction, Pg 5471, 3rd Paragraph). It is also very well known in the art that sodium azide has been widely used as a preservative (SIGMA-ALDRICH online, Merck Catalogue recites preparing a Nitro blue tetrazolium chloride staining solution by dissolving it in a buffer solution and heating it to 70°C. Moreover, particular motivation would have been derived from disclosures of Ishimaru et al., which teaches a method of measuring glycated protein in a sample by causing an oxidoreductase (an enzyme that catalyzes an oxidation-reduction or redox reaction) to act on glycated protein and measuring the amount of the product based on the action of the enzyme" (col.1, lines 61-66). Ishimaru et al. recites measuring a glycated protein for the purpose of the diagnosis of diabetes and further recites the method is applicable to a **general-purpose examining apparatus** with lower cost for a shorter period of time (Col 2, Lines 41-44).

Therefore, It would have been obvious to one of the ordinary skill in the art at the time of the instant invention was made, to use sodium azide as taught by Montellano in the method of measuring glycated hemoglobin as taught by Komori, because it would inhibit catalase. It has been well known in the art at the time the invention was made that sodium azide is an inhibitor of the catalase which is released as a result of

hemolzying erythrocytes and is responsible for the breakdown of hydrogen peroxide which in turn, can interfere with the measurement of the amount of glycated Hb in the method according to Komori et al. wherein the quantity of hydrogen peroxide formed corresponds to the quantity of glycated proteins in the erythrocytes. Sodium azide is widely being used in enzymatic assays to prevent bacterial contamination, there would have been a reasonable expectation of success at the time of invention was made to combine the steps of the method of measuring an amount of glycated protein taught by Komori in an apparatus that was recited by Ishimaru et al.

One of ordinary skill in the art would therefore have been motivated to use sodium azide in an assay solution as a means of preventing bacterial growth and increasing the accuracy of the measurement in an apparatus to obtain a better and more accurate measurement of glycated Hb. There would have been a reasonable expectation of success in using sodium azide in the method of Komori and also in an apparatus taught by Ishimaru for measuring the amount of glycated Hb, since at the time the invention was made all the steps of the claimed method, were well known in the art.

Accordingly the invention taken as a whole is *prima facie* obvious.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on 9:00 am to 5:30 pm EST Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kade Ariani
Examiner
Art Unit 1651

Leon B. Lankford Jr.
Primary Examiner
Art Unit 1651